vascular events, but substantial benefits attributable to weight (0.020) and especially hypoglycaemic events (0.024), related to CANA's better weight-lowering and longer time to initiation of insulin. **CONCLUSIONS:** Patients treated with CANA in triple therapy experienced an additional 0.039 QALY's over 40 years versus patients treated with SITA. The primary drivers were improved weight while on agent and fewer hypoglycaemic events.

PDB56

THE COST-EFFECTIVENESS OF DAPAGLIFLOZIN (FORXIGA®) VERSUS GLIPIZIDE IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM) IN ENGLAND AND WALES

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OBJECTIVES: Dapagliflozin (Forxiga®) is the first sodium-glucose co-transporter-2 (SGLT-2) inhibitor approved by the European Medicines Association, and positively assessed by the National Institute for Health and Care Excellence (NICE) for type 2 diabetes mellitus. This study investigates the cost-effectiveness of dapagliflozin compared with a sulphonylurea (SU) when added to metformin in patients inadequately controlled with metformin mono-therapy. **METHODS:** The published and validated CARDIFF diabetes model was used to conduct the analysis. Clinical inputs were derived from a randomized clinical trial comparing dapagliflozin and glipizide in combination with metformin. Based on these clinical inputs and the United Kingdom Prospective Diabetes Study (UKPDS) equations, the model predicts disease progression and the number of micro- and macro-vascular complications, along with diabetes-specific and all-cause mortality. The perspective of the National Health Service in England and Wales was adopted over a lifetime horizon. Local unit costs and utility data were assigned to the appropriate model parameters to calculate total Quality-Adjusted-Life-Years (QALYs) and total costs. Univariate and probabilistic sensitivity analyses (PSA) were conducted. **RESULTS:** Compared to SU added to metformin, dapagliflozin add-on to metformin was associated with an incremental benefit of 0.467 QALYs (95%CI: 0.420; 0.665) at an additional cost of £1,246 (95%CI: £613; £1,637), resulting in an ICER point estimate of £2,671 per QALY gained. The univariate analyses showed that no input parameter change inflated the ICER above £15,000 per QALY. The PSA showed that at a willingness-to-pay threshold of £20,000 per QALY gained, dapagliflozin treatment had an estimated 100% probability to be cost-effective compared to an SU treatment strategy. These findings were shown to be robust with all sensitivity analyses. **CONCLUSIONS:** Dapagliflozin in combination with metformin was shown to be a cost-effective treatment option for patients who are inadequately controlled with metformin mono-therapy within established UK cost-effectiveness thresholds.

PDB57

COST-EFFECTIVENESS OF DAPAGLIFLOZIN AS ADD-ON TO INSULIN FOR THE TREATMENT OF TYPE 2 DIABETES IN THE NETHERLANDS

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OBJECTIVES: Insulin, often combined with metformin, is usually the last therapy option for patients with type 2 diabetes Mellitus (T2DM) who are uncontrolled on oral anti-diabetic drugs. Dutch guidelines recommend up-titration of insulin until patients maintain an HbA1c <7%, yet in practice many patients never reach this target. Clinical evidence shows that dapagliflozin – a highly selective sodium-glucose cotransporter 2 (SGLT2) inhibitor – meets a need for these patients, i.e. by reducing HbA1c and weight. We studied the cost-effectiveness of dapagliflozin added to insulin (vs. not adding dapagliflozin) for patients with T2DM who have inadequate glycaemic control while on insulin. **METHODS:** We used the Cardiff Diabetes model to evaluate cost and effects of dapagliflozin added to insulin using direct comparative efficacy data from a randomized placebo-controlled trial (NCT00673231). In this trial up-titration of insulin was allowed in case of severe glycaemic imbalance. Risk factor progression and occurrence of future vascular events were estimated using the UKPDS 68 risk equations. Costs and utilities were derived from the literature. The analysis was conducted from a Dutch societal perspective using a lifetime horizon. **RESULTS:** The overall incidence of vascular complications was lower, and life expectancy was higher (19.43 LYs vs. 19.35 LYs) in those patients receiving dapagliflozin compared to patients not receiving dapagliflozin. Patients in the dapagliflozin arm obtained an incremental benefit of 0.42 QALYs. The lifetime incremental cost per patient in the dapagliflozin arm was € 2,293, resulting in an incremental cost-effectiveness ratio of €27,779 per LYG and an incremental cost-utility ratio of €5,502 per QALY gained. Sensitivity and scenario analyses showed that the results were robust to variation in modelling assumptions and input variables. **CONCLUSIONS:** This analysis shows that dapagliflozin increases the quality of life of T2DM patients compared to current practice (up-titration of insulin), and is cost-effective in a Dutch health care setting.

PDB58

THE COST-EFFECTIVENESS OF DAPAGLIFLOZIN (FORXIGA®) VERSUS INSULIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM) IN ENGLAND AND WALES

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OBJECTIVES: Dapagliflozin (Forxiga®) is the first sodium-glucose co-transporter-2 (SGLT-2) inhibitor approved by the European Medicines Association, and positively assessed by the National Institute for Health and Care Excellence (NICE) for type 2 diabetes mellitus. This study assesses the costs-effectiveness of dapagliflozin in combination with insulin versus insulin alone for patients who are inadequately controlled despite high doses of insulin. **METHODS:** The published and validated CARDIFF diabetes model was used to conduct the analysis. Clinical inputs were derived from a randomized clinical trial comparing dapagliflozin add-on to insulin with insulin regimens. Based on clinical inputs and the United Kingdom Prospective Diabetes Study (UKPDS) equations, the model predicts disease progression and the number of micro- and macro-vascular complications, along with diabetes-specific and all-cause mortality. The perspective of the National Health Service in England and Wales was adopted over a lifetime horizon. Local unit costs and utility data were assigned to the appropriate model parameters to calculate total Quality-Adjusted-Life-Years (QALYs) and total costs. Univariate and probabilistic sensitivity analyses (PSA) were conducted. **RESULTS:** Compared to insulin, dapagliflozin added to insulin was associated with 0.342 incremental QALYs (95%CI: 0.288; 0.480) at an additional cost of £1,813 (95%CI: £1,165; £2,381), resulting in an incremental cost-effectiveness ratio (ICER) point estimate of £5,295 per QALY gained. The univariate analyses showed that no input parameter change inflated the ICER above £15,000 per QALY. At a willingness-to-pay threshold of £20,000 per QALY gained, the dapagliflozin treatment strategy was estimated to have a 100% probability of being cost-effective when compared to the insulin treatment strategy. These findings were shown to be robust with all sensitivity analyses. **CONCLUSIONS:** Dapagliflozin was shown to be a cost-effective treatment option in combination with insulin for patients who are inadequately controlled with insulin alone within established UK cost-effectiveness thresholds.

PDB59

ASSESSMENT OF THE KEY DRIVERS OF COST-EFFECTIVENESS IN THE ECONOMIC MODELLING OF CANAGLIFLOZIN (CANA) VERSUS GLIMEPIRIDE (GLIM) IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM) IN THE UK SETTING

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OBJECTIVES: To evaluate uncertainty, the NICE reference case requires estimation of cost-effectiveness using alternative parameter values. Because models of T2DM necessarily include many parameters, NICE requirements dictate a large number of simulations. This study assesses the relative importance of common sensitivity analyses by identifying key drivers of the incremental cost-effectiveness ratio (ICER) using the example of CANA 300mg versus GLIM (titrated from 1mg to 6mg or 8mg), in combination with metformin in dual therapy. **METHODS:** The ECHO-T2DM model was used to simulate CANA versus GLIM over 40 years. ECHO-T2DM was loaded with patient characteristics, treatment effects, and adverse event rates from the DIA3009 trial. HbA1c was assumed to drift annually by 0.14% for CANA (similar to metformin in ADOPT), 0.24% for GLIM (as sulphonylurea in ADOPT), and 0.15% for rescue therapy with insulin (initiated when HbA1c >7.5%). Twenty-four one-way sensitivity analyses assessed the impact of drug durability, macrovascular risk equations, utility weights, and HbA1c goals. **RESULTS:** In the base case, CANA 300mg was associated with 0.21 greater QALYs at an incremental cost of £828, generating an ICER of £4,050/QALY. QALY gains were driven by fewer hypoglycaemic events and a better weight profile. The low acquisition cost of GLIM was partially offset by a greater need for insulin rescue therapy earlier in treatment, more hypoglycaemic events, and more macrovascular complications. Assuming no difference in durability for CANA and GLIM had the greatest impact on the ICER (£49,717), followed by no disutility for hypoglycaemic events (£15,733). The only other scenario having a noticeable impact was an HbA1c goal of 9.0% (£9,718). Alternative macrovascular risk engines had little impact on the ICER. **CONCLUSIONS:** The ICER was robust under a large number of scenarios. Only the difference in assumed long-term GLIM durability reversed the interpretation of CANA as cost-effective versus GLIM using NICE criteria.

PDB60

SOURCES OF LONG-TERM QUALITY ADJUSTED LIFE YEAR (QALY) GAINS FOR CANAGLIFLOZIN (CANA) VERSUS GLIMEPIRIDE (GLIM) IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS (T2DM) IN THE UK SETTING

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OBJECTIVES: The NICE reference case for T2DM requires cost-utility analysis with a lifetime horizon. The denominator in cost-utility outcomes is the incremental QALY, which is driven in most T2DM economic models by several key features, including: life extension, micro- and macrovascular events, treatment and treatment-related adverse events (AEs), and excess bodyweight. This analysis aims to determine which factors most impact QALY gains using the example of CANA 300mg versus GLIM (titrated from 1mg to 6mg or 8mg) when combined with metformin. **METHODS:** The ECHO-T2DM model was used to simulate CANA versus GLIM over 40 years. ECHO-T2DM was loaded with patient characteristics, treatment effects, and AE rates from the DIA3009 trial. HbA1c was assumed to drift upwards at an annual rate of 0.14% for CANA (similar to metformin in the ADOPT trial) and 0.24% for GLIM (as sulphonylurea in ADOPT). CANA and GLIM were discontinued and insulin initiated (annual drift 0.15% as in UKPDS) when patients failed to maintain HbA1c under 58 mmol/mol (7.5%). **RESULTS:** Hypothetical patients experienced 0.21 more QALYs when treated with CANA 300mg versus GLIM. Because GLIM was associated with greater use of rescue medication (and extra insulin-mediated HbA1c lowering) in the simulation, HbA1c values converged asymptotically limiting the differences in microvascular complications. However, lower blood pressure for patients on CANA versus GLIM was associated with reductions of 2.2% to 4.1% for the rates of macrovascular outcomes (although associated QALY gains were small due to discounting). Differences in weight and especially hypoglycaemic events, related both to GLIM and to earlier initiation of insulin, were associated with improvements in utility (0.04 and 0.16 QALYs, respec-

tively). **CONCLUSIONS:** Patients treated with CANA in dual therapy experienced an additional 0.21 QALYs over 40 years versus patients treated with GLIM. The primary drivers were improved weight while on agent and fewer hypoglycaemic events.

PDB61

COST-EFFECTIVENESS OF INSULIN DETEMIR IN T2DM PATIENTS POORLY CONTROLLED WITH NPH INSULIN IN POLAND

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OBJECTIVES: In Poland, where long acting insulin analogues (LAA) are not currently reimbursed in T2DM, it is crucial to select a group of patients for whom LAA may be particularly preferred. Based on NICE recommendation such patients are those treated with human insulin (NPH) but not achieving glycaemic control. Thus the aim of this study was to evaluate the cost-effectiveness of insulin detemir (IDet) when compared to NPH in subpopulation of poorly controlled T2DM as defined by HbA1c ≥8% and/or ≥1 episode of severe or nocturnal hypoglycemia recorded during ≥6 months of NPH treatment. **METHODS:** A validated computer simulation of diabetes model (IMS-CORE) was used to project long-term clinical and economic outcomes. Clinical effects in HbA1c improvement, BMI change and reduction in hypoglycemic episodes were modelled. Analysis was based on findings from the subgroups of the *PREDICTIVE* study – a real-world data trial – that closely reflects the defined target population. Two distinct insulin therapy regimens with IDet and NPH were evaluated: basal-supported oral therapy (BOT) and a basal-bolus (BB) regimen. Baseline cohort characteristics, disease progression and utility estimates were obtained from systematic literature review. Costs were obtained from Polish published data. The analysis was conducted from a public payer and patient perspective over a lifetime time horizon. Discount rates were 5% (costs) and 3.5% (outcomes). **RESULTS:** The mean QALY gain resulting from treatment initiation with IDet compared with NPH was 0,311 (BOT) and 0,451 (BB). Base-case incremental cost-effectiveness ratios (ICERs) were 38,136 PLN/QALY (9,113€) and 13,726 PLN/QALY (3,280€), respectively. At the current ICER threshold of 105,801 PLN/QALY (25,281€) in Poland, probability of IDet being cost-effective compared to NPH is 95% (BOT) and approaching 100% (BB). **CONCLUSIONS:** Based on generally accepted cost/QALY threshold values in the Polish settings, IDet was found to be a cost-effective option for T2DM patients with inadequately controlled diabetes.

PDB62

COST-EFFECTIVENESS ANALYSIS OF INSULIN DEGLUDEC COMPARED WITH CURRENT STANDARD OF CARE IN THE MANAGEMENT OF TYPE 1 AND TYPE 2 DIABETES MELLITUS IN THE SPANISH HEALTH SYSTEM

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OBJECTIVES: Insulin degludec (IDeg) is a basal insulin with an ultra-long duration of action for management of patients with type 1 (T1DM) and patients with type 2 (T2DM) diabetes. IDeg have demonstrated efficacious blood glucose control with less hypoglycaemic events and with an option for flexibility in dose time compared insulin glargine (IGlar). The objective was to assess the cost-effectiveness of IDeg in Spain, compared with IGlar. The analysis focused on subgroups of patients within three treatment regimens: T1DM, T2DM treated with basal insulin in combination with oral anti-diabetics (BOT) and T2DM treated with basal-bolus (BB). **METHODS:** A one-year cost-utility model driven by differences in hypoglycaemia was used. Two alternative utility approaches were used: in the first case, the utility gain was elicited from the clinical trials. In the second, published dis-utilities for hypoglycaemic events and self-monitoring blood glucose tests were used to calculate QALYs. Cost and utilities were also estimated for potential use of less blood glucose test strips. Three subgroups were analysed: those using twice daily IGlar, those with high risk of severe hypoglycaemia, and those obtaining extra utility from dosing flexibility. Unit costs pertained to public tariffs and reflected the payer perspective. Baseline incidence rates of hypoglycaemia and related resource use was derived from a Spanish observational study. **RESULTS:** IDeg was dominant for T1DM, T2DM BOT and T2DM BB switching from twice daily. T2DM BOT with high risk of hypoglycaemia was also dominant. As for patients benefiting from dosing flexibility the cost/QALY were 6,921€/QALY in T1DM, 9,244€/QALY in T2DM BOT, and 33,099€/QALY in T2DM BB. The use of the two different utility methods gave similar results. Univariate and probabilistic sensitivity analyses confirmed robust results. **CONCLUSIONS:** This analysis demonstrates that IDeg is a cost-effective option in Spain, when used in sub-groups of patients currently treated with long-acting insulin.

PDB63

EVALUATING THE COST-UTILITY OF FENOFIBRATE TREATMENT OF DIABETIC RETINOPATHY IN AUSTRALIA

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OBJECTIVES: Evidence from the landmark trials FIELD and ACCORD demonstrated that fenofibrate significantly reduces rates of diabetic retinopathy (DR) progression in type 2 diabetes patients (T2DM). This study evaluates the long-term cost-effectiveness of fenofibrate mono- and combination therapy for DR in Australia. **METHODS:** A seven-state Markov model simulated progression of DR based on data from the Blue Mountain Eye Study. Risk reductions for retinopathy progression were derived from FIELD for fenofibrate monotherapy (vs. placebo) and ACCORD for fenofibrate+statin (vs. statin alone). No additional benefits were assumed beyond 5 years (DR progression was the same with/without fenofibrate after year 5). Quality-adjusted life expectancy, direct costs and incremental cost-effectiveness ratios (ICERs) were reported over 10 years. Unit costs (2012 Australian dollars, AUD), resource use and utilities were taken from country-specific sources/expert opinion. Future costs and clinical benefits were discounted at 5% annually. Sensitivity analyses were performed. **RESULTS:** Fenofibrate monotherapy improved mean quality-adjusted life expectancy by 0.09 QALYs versus placebo due to fenofibrate patients spending more time in mild DR states. Direct medical costs were AUD 898 higher for fenofibrate monotherapy, with additional treatment costs partially offset by reduced cost associated with advanced DR (e.g. ophthalmologist time and laser treatment), leading to an ICER of AUD 10,221 per QALY gained. Similarly, fenofibrate+statin led to an improvement of 0.05 QALYs versus statin alone with an incremental direct cost of AUD 1,707. The ICER for fenofibrate+statin was AUD 33,350 per QALY gained versus statin alone. Sensitivity analysis showed that results were relatively insensitive to changes in a range of assumptions. **CONCLUSIONS:** The reduced risk of DR progression associated with fenofibrate treatment was projected to improve quality-adjusted life expectancy, with treatment costs partially offset by reduced costs of retinopathy care. ICERs indicated that fenofibrate therapy was in the range likely to be considered cost-effective in Australia.

PDB64

COST-EFFECTIVENESS OF INSULIN DEGLUDEC COMPARED WITH INSULIN GLARGINE IN A BASAL-BOLUS REGIMEN IN PATIENTS WITH TYPE 1 DIABETES MELLITUS IN THE UNITED KINGDOM

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OBJECTIVES: Insulin degludec (IDeg) is a basal insulin with an ultra-long duration of action for the management of patients with type 1 (T1DM) and patients with type 2 (T2DM) diabetes. IDeg has demonstrated effective blood glucose control with less hypoglycaemic events and with an option for flexibility in dose time compared to insulin glargine (IGlar). The aim of this analysis was to evaluate the cost-effectiveness of IDeg versus IGlar in adults with T1DM in the UK. **METHODS:** Meta-analysis data from two phase III clinical studies were used to populate a simple, transparent short-term model. The analysis was conducted from the UK National Health Service perspective and costs and benefits were calculated over a 12-month period. Sensitivity analyses were conducted to assess the degree of uncertainty around the results. In order to test the robustness of the results, two versions of the model were used. One applied disutilities derived from the SF-36 questionnaire used in the clinical trials, the other applied disutilities associated with the occurrence of hypoglycaemic events. In both approaches an additional utility gain was attributed to the benefit of dosing flexibility. Baseline incidence of hypoglycaemia was taken from a real-life study from the UK. Resource use associated with hypoglycaemia was documented in the clinical trials. Published tariffs were used as unit costs. **RESULTS:** The base-case ICERs were £12,637/QALY and £13,349/QALY in the two modelling approaches, which are below commonly accepted thresholds for cost-effectiveness. The results were robust and largely insensitive to changes in input parameters. **CONCLUSIONS:** This short-term modelling approach allows the economic evaluation of newer insulin analogues when advanced long-term modelling based on HbA_{1c} differences is inappropriate due to the treat-to-target nature of the clinical trials resulting in equivalent HbA1c levels. For patients in the UK with T1DM IDeg is a cost-effective treatment option compared with IGlar.

PDB65

COST-EFFECTIVENESS OF INSULIN DEGLUDEC COMPARED WITH INSULIN GLARGINE FOR PATIENTS WITH TYPE 2 DIABETES MELLITUS INITIATING INSULIN THERAPY IN THE UNITED KINGDOM

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OBJECTIVES: Insulin degludec (IDeg) is a basal insulin with an ultra-long duration of action for management of patients with type 1 (T1DM) and patients with type 2 (T2DM) diabetes. IDeg has demonstrated effective blood glucose control with less hypoglycaemic events and an option for flexibility in dose time compared to insulin glargine (IGlar). The aim of this analysis was to evaluate the cost-effectiveness of IDeg versus IGlar in adults with T2DM initiating insulin therapy in the UK. **METHODS:** Meta-analysis data from three clinical studies were used to populate a 1-year cost-utility model. The analysis was conducted from the UK National Health Service perspective. Sensitivity analyses were conducted to assess the robustness of results. Two versions of the model were tested, one applied disutilities derived from the SF-36 questionnaire used in the clinical trials, the other applied disutilities associated with the occurrence of hypoglycaemic events. In both approaches an additional utility gain was attributed to the benefit of dosing flexibility. Baseline incidence of hypoglycaemia was derived from a UK real-life study. Resource use associated with hypoglycaemia was documented in the clinical studies. Official tariffs were used as unit costs. **RESULTS:** Base-case ICERs were £15,705/QALY and £13,003/QALY in the two modelling approaches. Results were robust, with baseline rate of hypoglycaemia a key driver of results. Using hypoglycaemia rates from a subgroup of patients who experienced ≥1 hypoglycaemic event per year IDeg was highly cost-effective versus IGlar; with estimated ICERS of £4,706/QALY and £2,528/QALY. **CONCLUSIONS:** This short-term modelling approach allows the economic evaluation of newer insulin analogues when advanced long-term modelling based on HbA_{1c} differences is inappropriate due to treat-to-target trial design. For patients with T2DM on a basal-only insulin regimen, IDeg is cost-effective compared with IGlar and offers additional benefits to subgroups of patients, such as those suffering from recurrent hypoglycaemia.

PDB66

THE COST-UTILITY OF INSULIN DEGLUDEC COMPARED WITH CURRENT STANDARD OF CARE IN THE MANAGEMENT OF TYPE ONE AND TYPE TWO DIABETES MELLITUS IN BELGIUM

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